Part 1 General

Section 01 Department of Health and Human Services Grants Policy Development, Issuance, and Implementation

A. Purpose and Scope.

1. The purpose of this Grants Policy Directive (GPD) is to describe the several means by which the Office of Grants Policy, Oversight and Evaluation (OGPOE), under the Office of Grants (OG), Assistant Secretary for Resources and Technology, issues and manages Department of Health and Human Services (HHS) grants policy. It describes the purpose, characteristics, and responsibilities for the Grants Policy Directive (GPD) system, including grants administration manuals (GAMs) implementing GPDs generally and the Awarding Agency Grants Administration Manual (AAGAM) specifically; and Grants Policy Statements.

2. It also specifies review and approval requirements for policies and procedures which implement or supplement issuances by OG and includes a list of references to key requirements that apply to HHS grants administration.

3. This GPD applies to all HHS Operating Divisions/Staff Divisions (hereafter, "OPDIVs") with grant-awarding authority, whether for discretionary or mandatory grants, and to grants management staff and program management staff in those OPDIVs or acting on behalf of those OPDIVs, as indicated in the following sections. For this purpose, OPDIV refers to the Administration for Children and Families, the Administration on Aging, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the Office of the Assistant Secretary for Preparedness and Response, the Office of Public Health and Science, the Office of the National Coordinator for Health Information and Technology, and the Office of the Assistant Secretary for Planning and Evaluation.

B. HHS Grants Policy Issuance Vehicles.

1. HHS uses several complementary means of policy issuance to communicate grants management policies and procedures that are necessary to comply with statutory and regulatory requirements, as well as good business practice: (a) GPDs, ATs, and the GAMs, as part of the GPD system, and (b) grants policy statements. These grants policy documents are intended to reflect a hierarchy of policies and procedural guidance or to reach different audiences, and to result in consistent application across HHS and between HHS staff and recipients.

2. Grants Policy Directives.

a. GPDs are the highest level of internal departmental grants policy issuance within HHS. GPDs, which are issued by OG, are intended solely as an instrument of internal HHS management to require HHS staff to follow the policies and standards they set forth. They are not directly applicable to applicants for, or recipients of, HHS grants or cooperative agreements (hereafter, "grants").

b. GPDs present departmental grants policy in a succinct manner, with an emphasis on policy over procedure. GPD statements of policy are broad in scope allowing, wherever possible, flexibility in implementation.

c. GPDs apply to discretionary grants and, if indicated in an individual GPD, to mandatory grants. Section 5 of the GPDs is reserved for policies that apply to mandatory grants only.

d. GPDs are organized as specified in paragraph D. of this GPD and developed and issued as specified in paragraph E.

e. On occasion, when it is necessary to issue an HHS policy but there is not adequate time to develop or update a GPD or the nature of the requirement does not warrant coverage in a GPD (for example, it is a temporary requirement), the GPDs will be supplemented by ATs. ATs are intended to be short-term or interim policy guidance—either because the requirement itself is time-limited or because the requirement will be incorporated in a GPD during the next update.

f. OGPOE may also determine that there is a need for an HHS policy even if there is no external statute, regulation, or government-wide guidance that it is required to implement. If

OGPOE determines that a GPD should be issued, it will follow the process outlined in paragraph E.1.

g. OGPOE is responsible for overseeing OPDIV implementation of GPDs and ATs.

3. Grants Administration Manuals.

a. GPDs are not intended to be used alone. Rather they require more detailed implementation in the form of a grants administration manual.

b. The AAGAM, which is a joint undertaking of most of HHS OPDIVs and OGPOE, not only implements the GPDs, but also includes coverage of other policy areas, for example, ones that are of concern to at least several of the participating OPDIVs. The AAGAM is developed, formatted, and issued as specified in paragraphs D.2 and E.2.

c. The OPDIV Chief Grants Management Officer (CGMO) (see paragraph C.2 and GPD 1.03C.2) must do the following:

(1) After the effective date of this GPD, obtain OGPOE approval to undertake development of a self-contained OPDIV-specific grants administration manual, for example, an OPDIV wishing to convert from use of the AAGAM.

(2) For any OPDIV using an alternate manual (including use of alternate manuals approved before the effective date of this GPD), provide each implementing chapter (or other subdivision) to be issued by the OPDIV to OGPOE for review and approval before issuance. For grants-management related subjects not covered by GPDs, the CGMO must provide a copy of the chapter (or other subdivision) to OGPOE before sending it for final approval within the OPDIV.

(3) For any OPDIV relying on the AAGAM as its GPD implementation,

(a) Obtain OGPOE approval to develop an alternate issuance to one or more AAGAM chapters.

(b) Obtain OGPOE approval to provide supplemental policy and procedural guidance to an AAGAM chapter or

to add chapters to the AAGAM if they cover any subject matter not covered in the AAGAM. This approval requirement does not include "personalizing" a chapter by inserting organizational titles or selecting an option where the AAGAM requires such an entry or has made provision for such flexibility.

(4) Have sub-OPDIV-level implementations, if any, reviewed by the OPDIV grants policy office (under the cognizance of the CGMO) to determine if the proposed issuance(s) is consistent with GPDs and, as applicable, the AAGAM. Any sub-OPDIV implementation of the AAGAM is subject to OGPOE review and approval.

d. Each GPD issued after the effective date of this GPD must have an implementing GAM chapter in accordance with the following:

(1) For any OPDIV with OGPOE approval for its own GAM or for issuance of an OPDIV-specific chapter in lieu of AAGAM implementation, the CGMO must, within 9 months of the date of the GPD transmittal notice (TN) (see paragraph E.1.e), submit its implementation to OGPOE for approval.

(2) The AAGAM implementation of a GPD ready for OG issuance must be completed no later than 9 months of the date of the GPD TN.

(3) Any other proposed OPDIV implementation of a GPD under paragraph C.3.c.(3) must be submitted to OGPOE for review and approval prior to publication.

4. Grants Policy Statements.

a. The *HHS Grants Policy Statemen*t (HHS GPS) is a compilation of general grants administration policies and requirements that apply to recipients of HHS discretionary grants, distinguishing the requirements, as appropriate, by type of recipient or type of grant. It serves as the terms and conditions of award for these requirements and is used in conjunction with the regulations implementing Office of Management and Budget (OMB) circulars (see paragraph H), as well as public policy, program-specific, and award-specific requirements.

b. NIH maintains its own *NIH Grants Policy Statement* (NIH GPS). While much of the information provided in the NIH GPS is equivalent to that in the HHS GPS, the NIH GPS specifically addresses research and research-related matters that apply to NIH. The NIH GPS is cited as a term of award for all NIH awards.

C. Responsibilities for HHS Grants Policy Development and Issuance.

Several organizations and formally constituted bodies have responsibilities for HHS grants policy development.

1. OG, and specifically OGPOE, is organizationally responsible for HHS-wide grants policy matters.

2. Pursuant to GPD 1.03, each OPDIV with grant-awarding authority (currently those listed in paragraph A.3) is required to have a Chief Grants Management Officer (CGMO). Collectively, the CGMOs of all of the OPDIVs, along with OG, comprise the Executive Committee on Grants Administration Policy (ECGAP). This management-level body serves as a forum for information sharing, discussion of policy matters, and, when necessary, attempting to resolve conflicts related to HHS grants policy (see paragraph C.3).

3. The Policy Work Group (PWG), chaired by OGPOE and comprised of grants policy and operational staff representing all OPDIVs with grant authorities, advises OGPOE on GPDs. For those OPDIVs using the AAGAM and the HHS GPS, their PWG members also are responsible for drafting of the AAGAM and advising OGPOE on the contents of the HHS GPS. These individuals are expected to (1) make their respective CGMOs aware of PWG discussions and issues so that OPDIV positions are known and can be discussed by the PWG, thus limiting issues that have to be elevated to ECGAP, and (2) be empowered to speak for their OPDIVs when the PWG makes decisions and recommendations. The Office of the General Counsel (OGC) also is represented on the PWG. As appropriate, OPDIV or other HHS subject matter experts also join PWG deliberations.

D. Organization, Numbering, and Distribution of Grants Policy Directives and Implementing Grants Administration Manuals.

1. In general, GPDs follow the organization of the OMB Circular A-102 Common Rule and OMB Circular A-110 and their HHS implementations at 45 CFR part 92 and 45 CFR part 74, respectively. Policy presented in this manner closely mirrors the life cycle of the grants process and provides staff with consistency in the arrangement of grants policies.

Specifically, GPDs are arranged in the following major divisions or Parts, with Sections also generally following OMB sequencing:

1 General

2 Pre-Award

3 Post-Award

4 After-The-Grant

5 Mandatory Grants

2. The GPD numbering system is intended to provide more meaningful identifiers of individual departmental grants policy issuances.

a. The first position in the GPD designation is a single-digit number, ranging from 1 to 5, which identifies the major Part to which the GPD is assigned. Following a decimal point, a two-digit number, ranging form 01 to 98, identifies the specific Section (under a Part). The number 99 is reserved for OPDIV-level policies that are not addressed at the OG level. This is followed by a three-digit number, which is preceded by a decimal point. These policies are referred to as implementations and will be arranged sequentially.

b. Because the GPD system both anticipates and requires further implementation, while trying to achieve uniformity in the location of policy within HHS grants policy, the third position in the GPD citation identifies the implementing level. The 100 series is used for AAGAM chapters. For any OPDIV obtaining OGPOE approval for a separate GAM or for a separate chapter, the numbering will be addressed as part of the review and approval process.

(1) Following are examples of GPD and AAGAM numbering:

(a) The citation for the definitions section under Part 1 – General, would read:

GPD 1.02—with 1 representing the part, in this case "General," and .02 indicating the section. Similarly, GPD 2.01 indicates that the GPD is in the "Pre-Award" part and is the initial section in that part.

(b) The citation for the same sections in the AAGAM would be as follows: 1.02.102 and 2.01.101, the last three digits indicating the AAGAM.

(c) The AAGAM citations for policies not covered by a GPD are 6.99.101, 6.99.102, and so forth up to ,potentially, 6.99.199.

(2) In the event that, with OGPOE approval, an OPDIV deviates from or supplements an AAGAM chapter (apart from "personalization"), the OPDIV must use its organizational abbreviation in parentheses following the numbering for each applicable paragraph. For example, if HRSA deviates from or supplements, 1.02.102-3, the citation would be 1.02.102-3 (HRSA) or if FDA deviates from 6.99.103-5, the citation would be 6.99.103-5 (FDA).

3. Upon issuance of individual GPDs, a single copy of the directive will be forwarded by e-mail to ECGAP members. Concurrent with the e-mail distribution, GPDs with accompanying transmittals are posted on http://intranet/administrative/grantsinfo/.

4. OPDIVs must have a system in place for providing the GPDs to their staff following issuance by OG.

E. Processes for Developing and Issuing Grants Policy Directives and the Awarding Agency Grants Administration Manual

1. Grants Policy Directives.

a. Primary responsibility for the development and maintenance of GPDs is assigned to OGPOE.

b. On a periodic basis, consistent with known changes in government-wide or HHS requirements, OGPOE will undertake a review of all GPDs that are in effect in order to ensure that they are current and continue to reflect departmental grants management policies and priorities. To the extent that the need for significant, substantive change is identified, OGPOE will follow the process outlined in paragraph E.1.d.

c. The need for a new GPD may be identified by OGPOE, an OPDIV, or the PWG.

d. OGPOE will use the following process to draft and obtain appropriate input on a planned/updated GPD:

(1) OGPOE will initiate a concept paper (CP) outlining the need for a GPD/need for changes to a GPD, its proposed coverage, and approach for OPDIV review and comment. The CP will be sent to the OPDIV ECA representatives with a "cc" to each OPDIV's PWG member(s). OPDIVs are encouraged to broadly disseminate CPs to grants operational staff within OPDIV grants offices for review and comment. Obtaining broadly based comments during the initial stages of grants policy development facilitates policy consensus, thus reducing time spent in rework and conflict resolution.

(2) OGPOE will review the responses it receives on the CP and determine whether there are substantive differences of opinion between or among OPDIVs that need to be discussed in advance of drafting the GPD. The PWG and ECGAP will serve as the forums for discussion of varying positions. OGPOE will attempt, to the extent feasible, to reconcile positions that continue to differ; however, OG retains the final authority to proceed with GPD drafting and issuance.

e. Once finalized, a GPD (whether new or updated) will be issued by means of a TN signed by the Deputy Assistant Secretary for Grants. The TN will indicate any GPD superseded (in the event of an update), as well as any other information needed for implementation.

f. GPDs are effective immediately upon issuance by OG (that is, the date of signature by the Deputy Assistant Secretary for Grants as shown on the TN). Advance notification to OPDIVs concerning impending issuance of a GPD will be provided, as necessary, if the subject matter or complexity will require substantial preparation for effective implementation. In addition, OG may request that an AAGAM chapter be developed concurrently, rather than sequentially, with the GPD or may provide early notice to allow implementation in funding opportunity announcements or award terms and conditions.

2. Awarding Agency Grants Administration Manual Chapters.

a. Upon issuance/re-issuance of a GPD, the PWG representatives of the relevant OPDIVs will undertake the development of an AAGAM chapter.

(1) Those PWG members will work with OGPOE to determine responsibilities for drafting an implementing AAGAM chapter (for example, designation of a lead OPDIV) and a schedule that will allow timely implementation.

(2) The schedule must show an end date, that is, an implementation ready for OG issuance, no later than 9 months of the date of the GPD TN (see paragraph B.3.d(2)).

b. The initial draft will be shared by the drafters with OGPOE for review. Once OGPOE is satisfied that the AAGAM draft is consistent with the corresponding GPD or there is adequate rationale for differences, OGPOE will share the draft with the entire PWG for distribution for formal review and comment. Generally, 30 days will be allowed for that review. OPDIVs are encouraged to distribute drafts for comment broadly within the OPDIV, including to grants operational staff, program staff, and other affected offices/functions.

c. The OPDIV or OGC PWG member is responsible for collecting comments on behalf of the OPDIV or OGC and assembling them as a single set of comments as follows:

(1) Comments must be designated as “substantive” or “editorial.”

(2) The office or individual responsible for reviewing the comments and forwarding them for PWG consideration must ensure that they represent the commenting OPDIV’s/OGC’s position and are internally consistent.

(3) Comments that represent OPDIV-specific implementation considerations or questions of how the proposed policy may apply to a particular program should be answered within the OPDIV.

(4) To the extent possible, comments should be accompanied by practical examples of effect rather than hypothetical examples.

d. OGPOE will organize the comments for PWG consideration at one or more sessions.

e. The AAGAM draft will be updated, as appropriate, to reflect agreements reached by the PWG. PWG members are expected to consult with their management to ensure that the positions taken are acceptable. This process may be followed multiple times depending on the extent of changes and significance of the issues presented.

f. A similar process will be followed for any AAGAM chapters deemed necessary in the absence of a GPD, except that the PWG members will determine the schedule.

g. Once the PWG representative(s) of the participating OPDIVs agree with the draft, OGPOE will perform a final review (equivalent to the review it performs of any other GPD implementation).

h. AAGAM chapters will be issued by the Deputy Assistant Secretary for Grants under a TN that indicates filing instructions and chapters superseded and provides any additional information necessary for implementation.

i. As GPDs and AAGAM chapters are issued, steps should be taken to ensure that appropriate training and guidance are provided to grants operational and program management staff regarding the new policies. OGPOE will review with OPDIVs the training required to implement policy issuances. In addition, HHS and OPDIV training activities/programs that address grants and other administrative policies should include reference to GPDs, GAMs, or grants policy statements, as appropriate.

3. *HHS Grants Policy Statement*

a. The HHS GPS (initially issued by OGPOE in 2007) will be reviewed periodically for currency and continued need.

b. Individual changes to the HHS GPS will be communicated to OPDIVs through the use of page changes, along with an indication of the nature and reason for the change, effective date, and

instructions for incorporating in awards. OGPOE will coordinate with the OPDIVs, as appropriate, before making such changes.

c. Any comprehensive revision of the HHS GPS will be accomplished jointly by OGPOE and the PWG.

F. External Implementation of Grants Policy.

1. GPDs and grants administration manuals.

a. GPD and AAGAM transmittal memoranda will highlight applicability to applicants/recipients, if any, and will specify the action(s) to be taken by HHS staff, including the need for, and timing of, inclusion of a new or revised requirement in the terms and conditions of award. If an OPDIV proposes an alternate implementation, OGPOE review and approval is required.

b. For an OPDIV with OGPOE approval to use an OPDIV-specific GAM, in the memorandum forwarding the proposed implementation to OGPOE for review and approval, the OPDIV must indicate any anticipated direct impact on applicants/recipients beyond that specified by OG in the GPD TN.

c. For any GPD/GAM implementation that affects applicants/recipients, OPDIVs may follow their own procedures to inform the affected external constituency (the public generally, applicants, and/or recipients) how the applicable provisions will affect them. Unless specific language for an award term and condition has been provided for OPDIV use, OPDIVs are required to submit any external implementation (including any implementation that will vary from the standard language provided or any permissible alteration) to OGPOE for review and approval prior to use.

2. Implementation or supplementation of HHS grants administration regulations and other HHS regulations affecting grants.

a. Although the HHS grants administration regulations are comprehensive, there may be instances when supplementation of those regulations is necessary. In addition the regulations themselves may provide options that allow or require OPDIV implementation. Circumstances under which implementation or supplementation is appropriate or required include, but are not limited to, the following:

(1) Implementation of an option reserved to the OPDIV/awarding office in 45 CFR part 74 or 92, whether on an individual award or a class(es) of awards;

(2) The need for more explicit guidance where audits or other monitoring reveals compliance problems or lack of understanding of a policy area(s); and

(3) Requirements in statute or implementing program regulations that differ from the general administrative requirements.

b. Implementation or supplementation of the HHS regulations cited in paragraph H. below is considered an "external" implementation.

(1) An external implementation requires OGPOE approval if it falls under the type of changes specified in paragraph F.2.a.(2) or (3). This review and approval may be accomplished as part of the formal HHS regulation clearance process.

(2) To the extent that the implementing or supplementing language establishes additional or alternate requirements to those already subjected to an opportunity for public review and comment, those new requirements also must be published in the *Federal Register* for review and comment.

3. Grants Policy Statements. OPDIV implementation or supplementation of the award/post-award requirements of the HHS GPS must be approved by OGPOE. Changes to the NIH GPS after the effective date of this GPD also must be approved by OGPOE

G. Deviations

1. A deviation is any departure from a requirement in the GPDs, a GAM, a grants policy statement, or HHS grants administrative regulations that would apply to one or more applications or grants. Deviations with respect to requirements incorporated by reference in 45 CFR part 74 or 92; for example, the cost principles, also are subject to the following approval requirements. If policy deviations are included within an alternate issuance under paragraph B.3.c, the deviation provisions of this paragraph also apply.

a. A "single-case" (individual) deviation request is a deviation being sought for one application or grant only that arises on a case-

by-case basis. Individual deviations, including any mandated by Federal statute, must be appropriately implemented by the OPDIV head or by officials designated in the OPDIV's formal deviation procedures.

b. A "class" deviation request involves more than one grant for which the same type of deviation action is being requested. Class deviations mandated by Federal statute must be appropriately implemented by the OPDIV Head or officials designated in the OPDIV's formal deviation procedures. Class deviations not mandated by Federal statute must be approved by OGPOE or other authority within HHS, OMB (if the deviation is from an OMB requirement), or other cognizant Federal agency, and, if approved, implemented consistent with any limitations or other conditions of approval.

2. OPDIVs are responsible for establishing a process to review, document, and evaluate deviation requests, whether for individual or class deviations. A copy of all deviations must be maintained in the official award file as well as in a central deviations file.

a. Single-case deviations from the following types of requirements may be approved by the CGMO:

(1) Requirements in HHS grants administration regulations, if the provision is not based on statute;

(2) Requirements in individual GPDs;

(3) Requirements in individual AAGAM chapters; and

(4) Requirements in a grants policy statement that are not covered by paragraphs G.2.a(1) through (3) and are not based on statute.

b. All class deviations must be approved by OG.

c. Each deviation forwarded to OG for approval must indicate the concurrence of the CGMO. If the CGMO does not concur in a request, it should not be forwarded to OGPOE for consideration.

H. Documents Used in HHS Grants Administration

Listed below are key HHS-wide and government-wide documents used in the administration of HHS grants. HHS staff members are responsible for ensuring that the correct version of a regulation is cited or applied in any documents or correspondence.

1. Statutes.[1]

Administrative Procedure Act (APA) of 1946 - The statute (5 U.S.C § 551 et seq.) establishing various procedures for agencies, including the procedures for notifying and allowing the public the opportunity for review and comment on proposed Federal agency rulemaking.

Cash Management Improvement Act (CMIA) of 1990 - A statute (P. L. 101-453 (1990); 31 U.S.C. §§ 3335, 6501, and 6503) that regulates the timing of cash flow between States and the Federal government and payment of interest.

Federal Grant and Cooperative Agreement Act of 1977 - The Act (31 U.S.C. § 6301 *et seq*.) which establishes guidelines for distinguishing Federal assistance relationships from Federal procurement relationships. It addresses the difference between acquisition and assistance and requires the use of grants or cooperative agreements for the provision of financial assistance whereas contracts are used to acquire goods or services for the direct benefit or use of the Federal government. (AAGAM Chapter 2.02.102)

Federal Funding Accountability and Transparency Act of 2006 – A statute that requires Federal agencies and award recipients and subrecipients to post specified information about obligations of Federal funds exceeding $25,000 on a publicly available web site.

2. Regulations.

37 CFR part 401, Rights to Inventions Made by Non-Profit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements

45 CFR

part 16, Procedures of the Departmental Grant Appeals Board

part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments

part 82, Governmentwide Requirements for Drug-Free Workplace (Financial Assistance)

part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

part 93, New Restrictions on Lobbying

part 95, General Administration- Grant Programs (Public Assistance and Medical Assistance)

part 96, Block Grants

part 100, Intergovernmental Review of Department of Heath and Human Services Programs and Activities

2 CFR part 175, Trafficking in Persons

2 CFR part 376, Government-wide Debarment and Suspension (Non-procurement)

3. OMB Circulars and Guidance.

A-21, Cost Principles Educational Institutions (relocated 2 CFR part 220)

A-50, Audit Follow-up

A-87, Cost Principles for State, Local and Indian Tribal Governments (relocated in 2 CFR part 225)

A-89, Catalog of Federal Domestic Assistance

A-102, Grants and Cooperative Agreements with State and Local Governments

A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (relocated in 2 CFR part 215)

A-122, Cost Principles for Non-Profit Organizations (2 CFR part 230)

A-133, Audits of States, Local Governments, and Non-Profit Organizations

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